SENATE BILL 457

By Black

AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10, Part 1, relative to the distribution of certain legend drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 10, Part 1, is amended by adding the following as a new, appropriately designated section:

Section 53-10-110.

- (a) The provisions of this part shall not apply to a person, firm or corporation who distributes, donates or otherwise gives away a legend drug if:
 - (1) Such drug is distributed, donated or given to an organization that is exempt from federal income taxation under § 501(a) of the Internal Revenue Code as an organization described in § 501(c)(3) of the Internal Revenue Code;
 - (2) The primary purpose of such nonprofit organization is to collect legend drugs donated by another person, firm or corporation and distribute such drugs to indigent persons;
 - (3) The drugs are only distributed by an entity or practitioner licensed by a state agency and authorized to do so;
 - (4) The nonprofit organization does not accept or distribute any drug that is classified and scheduled as a controlled substance pursuant to title 39, chapter 17, part 4, or U.S.C. title 21, chapter 9; and
 - (5) Any legend drug so distributed, donated or given to such a nonprofit organization is not misbranded, out of date, deteriorated, or obviously tampered with, adulterated or damaged.

- (b) Before any legend drug is distributed to a person pursuant to this section, the nonprofit organization shall require the intended recipient or the intended recipient's representative to give written, informed voluntary consent.
- (c) The good-faith donor of any legend drug to a nonprofit organization meeting the requirements of subsection (a), to a nonprofit organization of the type specified in subsection (a) for free distribution, shall not be subject to criminal prosecution for a violation of this part, license revocation or suspension or civil damages arising from the condition of the drug, unless an injury is caused by the gross negligence, recklessness or intentional conduct of the donor.
- (d) A nonprofit organization specified in subsection (a) which in good faith accepts, donates, distributes or dispenses legend drugs pursuant to this section, shall not be subject to criminal prosecution for a violation of this part or civil damages resulting from the condition of the drugs unless an injury results from the gross negligence, recklessness or intentional conduct of the organization.
- (e) Any nonprofit organization that distributes legend drugs under this section shall maintain proper records of each distribution.
- SECTION 2. This act shall take effect July 1, 2009, the public welfare requiring it.

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